

Presumed consent to organ donation: 10 years' experience in Belgium

Paul Michielsens MD

J R Soc Med 1996;89:663-666

More than 30 years after cadaver kidney transplantation became a routine clinical procedure, organ shortage is still limiting its application, and the role played by legislation in this shortage remains controversial. Unfortunately, partisans of the two sorts of law—informed consent and presumed consent—have often argued from prejudice rather than objective evaluation. Experience with a presumed consent law in Belgium illustrates that the matter is more complex than usually acknowledged. In this review I focus on how the new law affected organ retrieval and the factors that influenced its acceptance by all parties.

THE BELGIAN PRESUMED CONSENT LAW

In this law absolute priority is given to the will of the deceased. Every citizen has the right to decide to be a donor or to refuse donation and no one can over-rule this decision. In the town halls of all cities and villages, forms are available for the citizens to register their will and the data are entered in a national computerized registry accessible only to the transplant teams. At any time individuals can modify their decision. If the deceased person did not register in this way, the presumption is that he or she was willing to be an organ donor. The permission of the family is not required for organ retrieval but organs may not be removed if the family takes the initiative to oppose donation. There is, however, no legal obligation to inform the family of the intended removal of organs. The law is also applicable to non-Belgian citizens resident in the country for more than six months.

The Belgian transplantation law discourages the use of living donors, declaring the practice permissible only in cases where comparable results cannot be obtained with cadaveric organs. Strictly speaking, the use of living unrelated donors is thus unlawful, although one centre still does it, without legal action from the authorities.

Why was the law enacted? Clearly the intention was to increase the number of organs available for transplantation. Several categories of persons are involved in this process—the donor, the donor's family, the potential recipient and the medical profession. As the interests of these groups conflict, every transplantation law will be a compromise¹.

Those who drew up the Belgian transplantation law tried to learn from the failures of other legal systems and to elaborate an ethically sound compromise that would be acceptable to all parties as well as ensuring an adequate supply of transplantable organs. The fundamental provision in this law is the absolute respect for the will of the deceased. Before starting the organ retrieval procedure the transplant coordinator must check the central registry by modem, and a print-out is kept in the medical record. This contrasts with many informed consent laws, where the will of the deceased is often unknown and even when expressed on a signed donor card can be over-ridden by the relatives. The second motivation was the perception that, although organ donation is usually regarded positively, when family members are confronted with the sudden death of a close relative they are overwhelmed by emotions and the decision on organ donation can be extremely traumatic. Under these difficult circumstances most families have ambivalent feelings about organ donation, and whatever their decision, persistent remorse can result. For those who are absolutely opposed, the law provides for the right to refuse donation. By not registering his or her will, the deceased person has accepted implicitly the possibility of becoming a donor; this makes it easier for the family not to oppose donation, by freeing them of any responsibility. Denial is one of the ways in which we cope with unbearable realities; it is not exceptional for a family to deny the whole problem of donation, and this right to ignore must be respected; it is one of the reasons why an obligation to inform the family was not included in the law. Another reason was to avoid delays and arguments as to who should be informed and how the information was to be given, which could render the doctors legally insecure. Not only total legal security but also freedom to act in the best interests of the bereaved family was felt essential in obtaining the collaboration of the medical profession.

INFLUENCE OF THE TRANSPLANTATION LAW ON THE PRACTICE OF ORGAN RETRIEVAL

To get insight into the influence of the law on the practice of organ removal, one must understand the reasons why the law was enacted and how organ donation was practised beforehand. Organ transplantation started early in Belgium,

and from the beginning there was a policy to promote the use of cadaveric donors. The Belgian centres were also among the first in the world to apply the criteria of brain death to potential organ donors. At the end of the 1960s 233 cadaver kidney transplants and 39 transplants from living donors had been performed in five university centres². Major efforts had been made to increase the number of donors by sensitizing the media and informing the public and the medical profession. However, the number of donors increased only slowly. In 1984–1985 only 20 kidneys per million inhabitants per year could be retrieved. In Belgium there was a tradition in teaching hospitals of doing necropsies routinely in the absence of a formal objection from the family. On this basis and without a specific law, organ retrieval for transplantation was performed for more than 20 years and not a single legal action was taken. This practice of presumed consent for necropsies is common in Continental Europe³. It goes back to the second part of the eighteenth century when necropsy legislation was elaborated in Austria by Von Swieten, the personal physician to Empress Marie Theresa. It was this law that allowed Carl von Rokitsansky (1804–1878) to develop in Vienna a pathology school that became a model for teaching hospitals. Belgium lived under Austrian rule during most of the eighteenth century, and conceivably this influenced the tradition of systematic necropsy for patients dying in teaching hospitals. In the first years of transplantation, organ removal was limited to these teaching hospitals and the need for specific legislation was not felt. Potential donors come as a rule from intensive care units, and in the early days of transplantation these were mainly located in teaching hospitals. Later, many such units were opened in non-university hospitals where there was no tradition of routine necropsy, and it proved difficult to involve these units in the donation process in the absence of the security provided by a law. A second factor was the development of transplantation of organs other than the kidneys, which made multiorgan retrieval necessary. Doctors who were willing to take responsibility for the limited intervention of kidney retrieval were reluctant to proceed with multiorgan donation without explicit legal protection. The necessity for formal legalization of organ retrieval became even more obvious when the chairman of the nephrology department of the recently founded University of Antwerp started a vigorous campaign in the media, challenging the presumed-consent principle and promoting informed consent. There were fears that the end of consensus among the teaching hospitals, with resultant publicity in the media, would ruin 20 years of efforts to establish an efficient transplantation programme. In fact the opposite occurred. After 2 years of passionate and sometimes emotional discussions, widely publicized, the presumed-consent transplantation law was voted through in the Senate and in the House of Representatives by a large

majority from all political parties. The law is obviously accepted by most people and its application is no longer a matter of controversy. Less than 2% of the population have registered an objection to organ donation.

After the implementation of the transplant law in 1986, the kidney retrieval rate rose in 1987–1988 by 86% to 37.4 per million population per year. This increase in cadaveric donations was sustained and the number of living donors decreased progressively as shown in Figures 1 and 2. It would be of interest to analyse separately the evolution of the donor reporting in the teaching and non-teaching hospitals; unfortunately, such data are not available for the country as a whole. In Leuven we founded in 1978 a collaborative group for transplantation with the active participation of non-university departments of nephrology. Until 1986 this had only limited results and fewer than five of the associated centres contributed to the organ retrieval. After 1986 the number of collaborating hospitals with donor activities increased to 15⁴. In 1995 the non-university centres accounted for 77% of the organ retrievals of the Leuven group. The Belgian law obviously provided a legal environment favourable to the collaboration of intensive care units in non-university hospitals.

In the absence of a registered will of the deceased, the law leaves considerable freedom to the medical profession. As might be expected, the practical application was variable

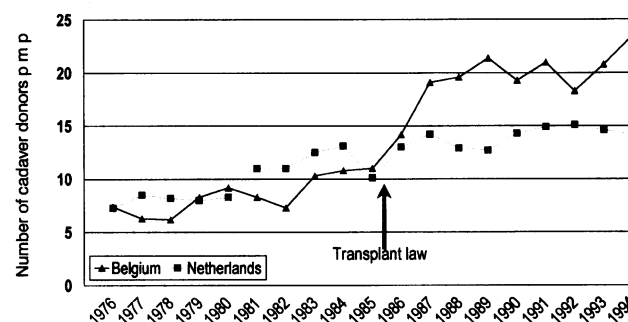


Figure 1 Evolution of the number of effective cadaver donors per million population per year in Belgium and in the Netherlands [Data from the Eurotransplant annual reports]

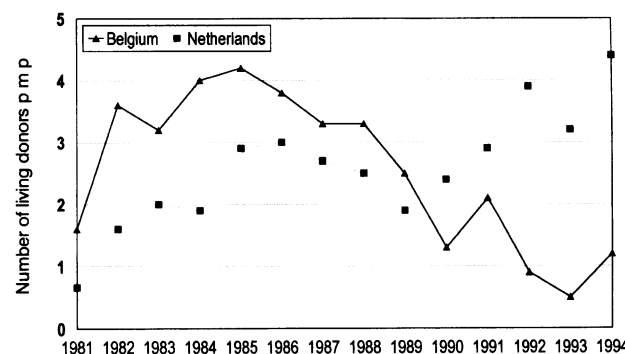


Figure 2 Evolution of the number of living donors per million population per year in Belgium and in the Netherlands [Data from the Eurotransplant annual reports]

and the group in Antwerp continued to seek explicit permission of the relatives with the active involvement of a transplant coordinator in contact with the family. It is noteworthy that, after the introduction of the new law, the retrieval rate was unchanged in Antwerp—a strong argument against the hypothesis that the increase in the number of donors was due to the publicity⁵. Confronted with the persistent shortage, Antwerp lately decided to abandon the strict informed-consent practice. Unexpectedly, a group in Brussels that had until then supported and applied the presumed-consent principle changed to informed consent. Although the contrary is explicitly stated in the legislation, the group felt that the provision of the law granting the family the possibility to oppose donation implied the obligation to ask explicitly for permission. In this centre as in Antwerp, enactment of the law had no influence on the number of organs retrieved. There was no clear difference in attitude between the Flemish and French speaking parts of the country. The determinant factor was the stance of the head of the department. It would, however, be wrong to conclude that families are rushed from the death room without an explanation or that they are confronted with a scar they did not expect on the body of their loved one. As a rule when death is notified, the family is informed of the intention to proceed with organ removal, but explicit permission is seldom asked. This information is usually given by the doctor in charge and not by the transplant coordinator, whose role is often limited to technical and administrative support. No information is given when the family shows total lack of interest or when the relatives cannot be contacted in due time. Since many donors come from non-teaching hospitals, there is a wide variation in attitudes and there are no reliable statistical data on the way in which the information is given to the family or on the number of cases in which the family made use of its right to oppose donation. The main factor in the positive attitude of the medical profession to the law is without doubt the legal security. The doctors responsible for the donor can decide freely how much information is given, how it is given and to whom, without risk of being sued. In retrospect and in comparison with the earlier situation, the law has resulted in more openness. Being informed of the intention to proceed with organ removal has proved a less traumatic experience for the family than a request for permission to proceed. The absence of "horror stories" in the media indicates that the medical profession has applied the law in a sensible and humane way.

COMPARISON BETWEEN COUNTRIES WITH DIFFERENT LEGISLATIONS

From Table 1 it is clear that, among the countries participating in Eurotransplant, the two with a presumed

consent law, Austria and Belgium, outperform in number of donors Germany and the Netherlands, where formal permission of the family is required. One must, however, be cautious in drawing conclusions about cause and effect. The organ retrieval rate is the final result of different factors and events. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The number of possible donors is determined by, among other things, the density of the population and its age stratification, the number of traffic accidents, the number of intensive care units and the social security system. The law can obviously only modify the motivation of the medical profession and of the public. Although the differences in overall retrieval rate are impressive, the influence of the type of law on number of donors can still be questioned. More convincing is the fact that the proportion of multiorgan donors is also significantly higher in the setting of a presumed consent law. If we consider the mean values of the last five years within Eurotransplant, it can be calculated from the data in Table 1 that the mean retrieval rate per million inhabitants in the countries with a presumed consent legislation was 65% higher for kidneys, 71% for lungs, 100% for pancreases, 110% for livers and 145% for hearts.

What can be said about the evolution of the donor rate in Belgium compared with the Netherlands (Figure 1)? Until 1986 neither country had a specific transplantation law and organ removal was performed according to the rules for necropsies. In the Netherlands the legal basis for organ retrieval is still a law dating from 1869, regulating the disposal of the bodies and stating that for a necropsy a will of the deceased or the permission of the relatives is necessary. Informed consent has thus been the rule for organ retrieval in the Netherlands, as in the Anglo-American legislations. Legislation apart, Belgium and the Netherlands have in common a high density of population, a well developed social security system and a large number of hospitals with adequately functioning intensive care units. In both countries transplantation started early. Some have argued that differences in the number of road accidents explain the differences in organ retrieval. In 1992 the number of road deaths per million population (pmp) was 171 in Belgium

Table 1 Annual number of organs retrieved per million population. Mean values for 1993–1995 [Data from Eurotransplant]

	Kidney	Liver	Pancreas	Heart	Lung
Belgium	39.9	13	1.6	12.1	5.7
Austria	46	14.7	2	12.6	6.3
Germany	24.2	5.9	0.6	5.8	1.5
Netherlands	27.9	7.3	1.2	4.3	2

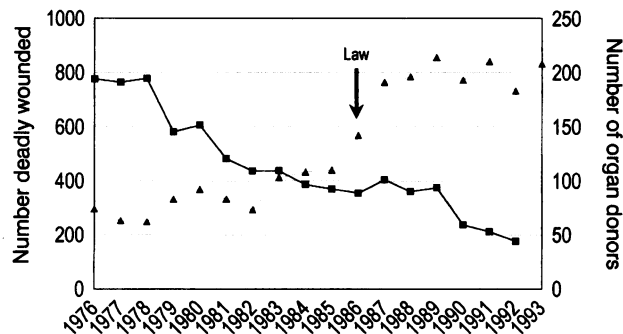


Figure 3 Number of road accident patients dying within the first days after admission to an intensive care unit (squares). Number of effective organ donors irrespective of cause of death (triangles). [Data from the Belgian Institute for Traffic Safety and from Eurotransplant. Reprinted from ref 5 with permission]

against 91 in the Netherlands. The importance of this factor is not as overwhelming as it seems at first sight, because traffic deaths include people who died "on the spot" and who are, as a rule, not available as organ donors. The potential donors are mortally injured, i.e. those who die within the first days after admission to an intensive care unit. From the 171 road deaths per million population in Belgium in 1992, less than 20 per million population were mortally injured. When the transplantation law was enacted in 1986 the number of mortally injured was 40 pmp; it decreased progressively to 20 pmp in 1992, while the number of organ donors doubled (Figure 3). According to the 1994 Eurotransplant annual report, the cause of donor death was an accident in only 43.7% of the Belgian donors, against 42% for Eurotransplant and 36.9% for the Netherlands. This marginally higher number of accidental deaths among the donors is insufficient to explain the difference in retrieval rate between the two countries. Another interesting point in the comparison between the two countries is the finding that, until 1986, the retrieval rate was nearly identical although informed consent was the rule in the Netherlands and presumed consent was practised in Belgium. This indicates that there is much more in the presumed-consent law than the possibility of retrieving organs without explicit permission from the relatives. Important is the absolute legal security and the official statement that donation is the rule, with some exceptions. The opportunity for the doctors in charge of the donor to decide if, how and to whom the information is given has also been a major factor in the development of decentralized organ retrieval. The importance of this factor is confirmed by experience in Austria, where in 1981 a presumed-consent law was passed, confirming the practice based on the necropsy tradition.

The number of donors did not change until 1984, when a decentralized model of donor procurement was developed in Vienna and Linz^{6,7} and led to a 100% increase in these two centres. The Belgian and Austrian experiences suggest that both the presumed-consent law and the decentralized donor procurement are essential elements for efficient organ retrieval.

No transplantation law can operate efficiently without acceptance by the public. Despite apprehensions to the contrary, the presumed-consent law generated no objections from the public. The question whether a similar law would be equally acceptable in countries with a different historical and cultural background is a matter for speculation. The decision to proceed with organ retrieval in the setting of brain death is a traumatic experience. Under an informed-consent law, the burden of responsibility for the decision is put on the family, and the task of asking for consent is usually delegated to a transplant coordinator. The freedom given by the presumed-consent law has as corollary the fact that the primary responsibility is now put on the doctors. Doctors feel responsible for the patient and the patient's family, and are less directly concerned about the needs of the community. This could explain the reluctance of some to make use of all the possibilities offered by the law. It illustrates the difficulty of coping with a situation which is new in medical practice. Overall the results have been favourable and we can hope that, confronted with these new responsibilities, the medical profession will steadily adapt.

REFERENCES

- 1 Michielsen P. Organ shortage—what to do? *Transplant Proc* 1992;24:2391–2
- 2 Alexandre GPJ, Derom F, Godon JP, et al. Etat actuel de la transplantation rénale en Belgique. *Acta Chirurg Belg* 1970;69:409–24
- 3 Svendsen E, Hill RB. Autopsy legislation and practice in various countries. *Arch Pathol Lab Med* 1987;111:846–50
- 4 Vanrenterghem Y, Waer M, Roels L, Lerut T, Gruwez J, Vandeputte M, et al. On behalf of the Leuven Collaborative Group for Transplantation. In: Terasaki P, ed. *Clinical Transplants 1988*. Los Angeles: UCLA Tissue Typing Laboratory, 1988:91–7
- 5 Michielsen P. Effect of transplantation laws on organ procurement. In: Touraine JL, et al., eds. *Organ Shortage: The solutions*. Dordrecht: Kluwer, 1995:33–9
- 6 Mühlbacher F. Donor recruitment in Austria. In: de Charro FTH, Hessing DJ, Akveld JEM, eds. *Systems of Donor Recruitment*. Dordrecht: Kluwer, 1992:65–71
- 7 Gnant MFX, Wamser P, Goetzinger P, Sautner T, Steiniger R, Mühlbacher F. The impact of the presumed consent law and a decentralized organ procurement system on organ donation: quadruplication in the number of organ donors. *Transplant Proc* 1991;23:2685–6